Section III - SMDA Summary of Safety and effectiveness – "510(K) Summary"

OCT 13 2011

K111978

1. Submitter Information:

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Date summary prepared: June 30th , 2011

2. Device name

Trade Name:	**SULCUSBLUE**
Common/Usual Name:	Gingival retraction/Hemostatic paste
Classification Name:	Unclassified
Product code:	MVL

3. Devices for which Substantial Equivalence is claimed:

- ***HEMOSTASYL*** (PRODUITS DENTAIRES PIERRE ROLLAND) K082116 dated 12/17/2008
- ***EXPASYL*** (PRODUITS DENTAIRES PIERRE ROLLAND) K050180 dated 02/11/2005
- ***TRAXODENT*** (PREMIER DENTAL PRODUCTS CO) K083695

4. Device description

SULCUSBLUE is a paste containing aluminium chloride which is used, in association with compression caps (SULCUSCAP), for the temporary retraction and hemostasis of the gingival margin during dental procedures such as dental impressions.

The paste is applied directly into the sulcus thanks to the a cannula. It is left in place between 1 and 2 minutes depending upon the tonicity of the marginal gingival and removed by an air and water spray with simultaneous aspiration. A dry retracted sulcus is obtained.

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5. Intended use of the Device

SULCUSBLUE is a paste containing aluminium chloride which is intended to be used, in association with compression caps, for the temporary retraction and hemostasis of the gingival margin during dental procedures such as dental impressions.

6. Substantial Equivalence:

SULCUSBLUE is substantially equivalent to other legally marketed devices in the United States: HEMOSTASYL, TRAXODENT and EXPASYL are intended for a similar use (gingival retraction and hemostasis during dental procedures).

7 Safety of the Device

Hereafter a comparative table regarding the composition of SULCUSBLUE with the other products: EXPASYL and HEMOSTASYL:

	SULCUSBLUE	EXPASYL	HEMOSTASYL
Kaolin	X	X	X
Aluminium chloride hexahydrate	**15%**	**15 %**	**15%**
Purified water	X	X	X
Dye	X	X	X
Anhydrous colloidal silica	X	-	X
Propylene glycol	X	-	X
Strawberry Aroma	X	-	X

Because SULCUSBLUE and HEMOSTASYL have exactly the same composition, we can use for SULCUSBLUE the results of the test performed on HEMOSTASYL:

- **Tolerance study of a dental paste on the injured oral mucosa in the Hamster**

  (study TL 537 /05-2908 dated January 13th, 2006)

  Method: according to NF EN ISO 10 993-10 standard February 2003.

Group 1 (control): 0.9% NaCl solution

Group 2 (treated): 0.5ml of HEMSOTASYL (same composition than SULCUSBLUE)- Contact time : 3 minutes* then rinsed with

0.9% NaCl solution

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Results and conclusion: Under the experimental conditions adopted, HEMOSTASYL applied on the scarified mucous membrane of the cheek pouch of the Hamster stopped immediately the bleeding ; it did not induce any systemic toxicity signs. Locally, after 5 days an irritation reaction considered as begnin was noted on the lesion treated with HEMOSTASYL ; it was totally reversible within14 days.

The complete report is presented in Appendix G.

* Under normal conditions of use the contact time of HEMOSTASYL is 2 minutes. The contact time has voluntarily been increased in this test in order to be in the "worse case".

CONCLUSION :

Regarding the different results obtained, it appears that SULCUSBLUE stops the bleeding and has a good local and systemic tolerance

According to the results obtained, SULCUSBLUE is substantially equivalent to predicate devices as well as the legally marketed retraction and hemostatic paste.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 1 3 2011

Produits Dentaires Pierre Rolland
C/O Mr. Rick Rosati
Quality Manager
ACTEON, Incorporated
124 Gaither Drive, Suite 140
Mount Laurel, New Jersey 08054

Re: K111978
Trade/Device Name: SULCUSBLUE
Regulation Number: None
Regulation Name: Unclassified
Regulatory Class: None
Product Code: MVL
Dated: September 7, 2011
Received: September 8, 2011

Dear Mr. Rosati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K111978

Device Name: **SULCUSBLUE**

Indications For Use:

SULCUSBLUE is a paste containing aluminium chloride which is intended to be used, in association with compression caps, for the temporary retraction and hemostasis of the gingival margin during dental procedures such as dental impressions.

Please refer to the attached file for a complete description.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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